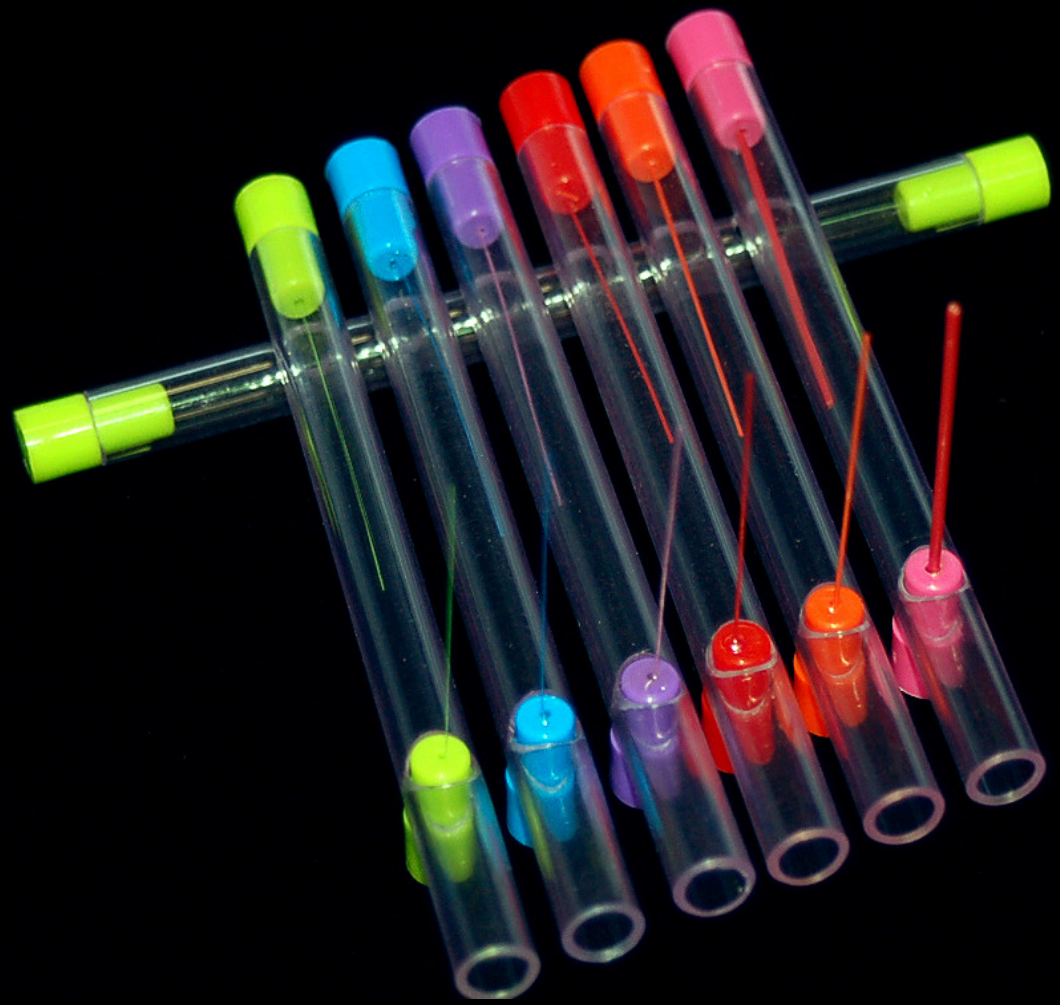
SORRI ® MONOFILAMENT AESTHESIOMETER

TOUCH SENSITIVITY TESTING KIT

User's Manual



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Pat.Pending

PRECAUTIONS

- Read this Manual carefully and study the instructions before you use the instrument.

- If any doubt should arise as to the correct procedure in any specific situation, please consult the qualified personnel at SORRI-BAURU.

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INTRODUCTION:

The SORRI-BAURU Touch Sensitivity Testing Kit is a "Synthetic monofilament aesthesiometer".

INTENDED USE:

The sense of touch afforded by our nervous system is an important point of contact with the world around us. It permits the perception of objects, helps to protect the skin and underlying tissues against damage, providing the rapid perception of light touch or deep pressure and discriminating between rough and smooth, movement or vibration, a gentle contact or a sharp point.

Changes in the tactile perception threshold of the skin can impair this ability we have to protect us from dangerous objects or eventualities around us.

The SORRI aesthesiometer kit serves to evaluate and monitor the degree of skin sensitivity to forces applied as stimuli to the nerves which should be sensitive to light touch and pressure. The forces are graded in steps reflecting the functional thresholds considered most critical for the hands and feet, (Bell-Krotoski, 1989) composed of six force levels between 0.05 gf (0.49 mN) and 300 gf (2.94 N).

Thus, the instrument allows detection and monitoring of functional alterations of the patient's peripheral nerves. In diabetes and leprosy, as well as other diseases that cause debilitating neuropathies, early detection of such changes is fundamental in order to prevent disability, prevent injuries and reduce risk of amputations.

PRINCIPLES OF OPERATION:

- A nylon filament tends to bend elastically when a compression force applied axially reaches a critical value (LEVIN et al 1978).

- Under typical laboratory or clinic conditions, this critical force depends on the elastic modulus of the nylon, the monofilament length and its diameter.

- In these conditions the elastic modulus is constant, while the diameter and length are carefully controlled in the manufacturing process of the instrument.

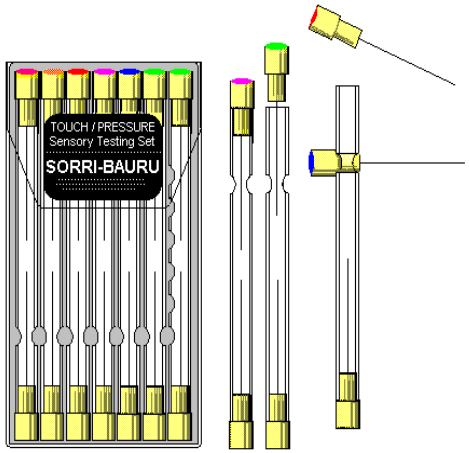
- Thus, when properly applied, a clear sign (curve of the filament) appears when the critical force, known for each filament, is applied via the filament.

- Even if the filament suffers slightly more compression or a slight vibration, the elastic curvature of the filament effectively helps maintain a constant applied force. (BELL-KROTOKI, 1989)

BACKGROUND:

• After several attempts to introduce and spread through Brazil a practical method for the evaluation of functional changes in the cutaneous touch sensitivity of people with leprosy, professionals from American Leprosy Missions (ALM) brought the problem to SORRI-Bauru – an innovative Brazilian non-profit involved in the rehabilitation process, with a focus on the stigma and social rejection problems associated with leprosy. Through its vocational training activities, SORRI had an already prominent programme for development of assistive technology and special products.

• In collaboration with ALM and the Lauro de Souza Lima Hospital (now a Research Institute), SORRI-Bauru's product designer developed a portable instrument, robust, reliable and easy to use in the clinic or in the field, even in adverse conditions (LEHMAN et al.1993).



- The Kit developed by SORRI-Bauru, follows Sidney Weinstein's proposal to use mounted nylon filaments of equal lengths, varying only their diameter (WEINSTEIN, 1962).

- Weinstein, as is known, based his ideas on the experimental work of the European physiologist Maximilian Von Frey, who used animal hairs, calibrated to provide precise stimulus values, (Von FREY, 1922).

CHARACTERISTICS AND USE OF THE INSTRUMENT

- The **SORRI touch sensitivity testing kit** is designed as a simple and convenient means of detecting and monitoring functional alterations in the peripheral nerves.

- It consists of a flexible plastic wallet containing a set of seven tubes, each containing a pair of special nylon filaments.

- Six of the tubes are drilled transversally to provide **mounting holes** to maintain the filament in the correct position for use.

- Each tube has two nylons, one of which is a reserve.

- To facilitate interpretation, a colour-code is used to indicate the approximate axial force necessary to bend each filament.

- The Kit also contains a tube with a spare set of the most delicate filaments (0,05 g – green) and the set of holes in this tube allow it to be used as a convenient support for the other tubes when they are mounted for use.

- Other combinations of filaments may sometimes be available – for example, single tube packs, with a particular filament and its reserve, for use in specific screening tests.

- Each wallet contains an explanatory leaflet with instructions for care of the instrument and information about its use. It also provides suggestions to facilitate mapping of the results and a grid to assist with interpretation of the results.

EXAMINATION PROTOCOL:

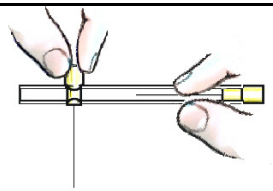
To ensure reliability of the test, it is fundamental to carefully follow a standard procedure.

- The validity of a sensory test is dependent on rigorous adherence to a standard procedure.
- The testing should take place in a calm environment, without noise or distractions.
- Tactile sensation may alter with temperature. Allow the patient who has just come in out of strong sunshine, or from the cold, enough time to adjust to normal temperature.
- Prepare mapping evaluation sheets and colour pens prior to testing. Careful documentation facilitates case-analysis and the use of colour-coding helps to quickly interpret observations.
- The following procedure should first be demonstrated on an area of skin where there is good sensitivity and the subject can observe the process.
- When the patient understands the testing procedure, his vision is excluded and the tester begins the sensory test, documenting as threshold the first affirmative response in each site tested.

In Hansen's disease, the WHO Disability Grading of Grade 1 is documented when any palmar or plantar area has a LOSS of PROTECTIVE SENSATION. Therefore any area where the first positive test response is to a 4.0 gf, or heavier filament, (red or black area) should be documented as a GRADE 1 DISABILITY.

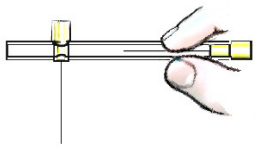
MOUNTING and USING the MONOFILAMENTS:

1



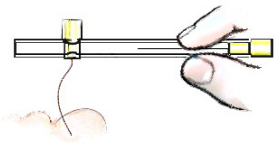
- Withdraw from the tube the filament nearest to the mounting holes, and introduce it carefully through the transversal mounting holes until the support is firm. Prepare one filament of each colour.
- The other filament remains in the protective tube as a reserve.
- Damaged, kinked, or bent filaments should be discarded and replaced with a new filament of the same specifications.

2



- Hold the tube so that the nylon filament is perpendicular to the subject's skin, but not touching.
- The test begins with the lightest filament, (green) and continues through progressively heavier filaments until a positive response is obtained.
- Without letting the patient see, touch the nylon to the skin with a smooth, gentle pressure, which just causes the nylon to bend. The pressure is maintained for about 2 seconds and then the filament is lifted smoothly away.
- If the nylon slides over the skin, the test at this site should be repeated.

3



- Ask the patient to say "yes" when he feels the filament.
- Apply the green and blue filaments up to three times at each test site before confirming absence of sensitivity at this level.
- Never use the same filament on more than 10 patients a day - utilise the reserve filament.

!

- Filaments should be cleaned by washing the nylon very carefully with 70% alcohol and/or warm soapy water, after which the nylon is rinsed with water, but not left to soak.
- These filaments should not be used on the eyes, or mucous tissue, or open wounds. In the case of ulcers, scars, or callus tissue, perform the test on a nearby site, within the same peripheral nerve territory.
- To avoid damaging the filaments while replacing them carefully in their protective tubes after use, it is helpful to block the mounting holes by holding the tube between finger and thumb.

TRADITIONAL THRESHOLD MAPPING PROTOCOL

Perform the evaluation in the sequence listed below, and for each site tested, document the first nylon that has a positive response.

Lightest filament whose touch can be felt:	INTERPRETATION	Suggested mapping code:
Green (Nominal: 0.05 gf)	- Sensation within normal limits for the hand and foot.	Green filled circle
Blue (Nominal: 0.2 gf)	- Diminished light touch sensation in the hand with difficulty in fine tactile discrimination. Within normal limits for the foot.	Blue filled circle
Purple (Nominal: 2.0 gf)	- Diminished protective sensation in the hand but sufficient to prevent injury. Gross tactile discrimination, shape and temperature discrimination are difficult.	Purple filled circle
Dark Red (Nominal: 4.0 gf)	- Loss of protective sensation for the hand; in some cases for the foot. Hands particularly vulnerable to injuries. Usually, loss of temperature discrimination.	Red filled circle
Orange (Nominal: 10 gf)	- Definite loss of protective sensation for the foot. Pressure and pain may still be felt in hands and feet.	Red cross
Light red/ Pink (Nominal: 300 gf)	- Still able to feel deep pressure and pain.	Red circle
No response	- Loss of deep pressure sensation. Usually does not feel pain. Proprioceptive function may persist.	Black filled circle

EQUIVALENCE WITH OTHER TESTS AND ASSOCIATED FUNCTIONAL LEVELS:

Correlation between functional skin sensitivity thresholds and traditional tests was first observed by Von Prince & Butler (1967).

Threshold	Equivalence	
Green: (Nominal: 0,05 gf)	**Normal sensation** (Threshold ≤ 0.05gf) -Touch-discrimination of symbols traced on the skin (graphaesthesia) retained. -Light touch and texture discrimination retained.	-Shape (stereognosis) and temperature discrimination retained. -Deep pressure and pain sensation retained. -Awareness of position and movement (proprioception) retained.
Blue: (Nominal: 0,2 gf)	**Diminished light touch sensation:** (0.05 gf < threshold < 0.2 gf) -Loss of graphaesthesia. -Difficulty with fine texture discrimination.	-Shape and temperature discrimination retained. -Deep pressure and pain sensation retained. -Proprioception retained.
Purple: (Nominal: 2,0 gf)	**Diminished protective sensation:** (0.2 gf < threshold < 2.0 gf) -Loss of graphaesthesia. -Loss of fine texture discrimination	- Difficulty or loss of stereognosis and thermal discrimination. -Deep pressure and pain sensation retained. -Proprioception retained.
Red: (Nominal: 4,0 gf) **Orange:** (Nominal: 10,0 gf)	**Loss of protective sensation:** (threshold < 4.0 gf for hand) (threshold < 10.0 gf for foot) -Loss of graphaesthesia. -Loss of fine texture discrimination	-Loss of stereognosis and usually thermal discrimination. -Deep pressure and pain sensation retained. -Proprioception retained.
Light Red: (Nominal: 300 gf)	**Deep pressure sensation:** (10.0 gf < threshold < 300 gf) -Loss of graphaesthesia. -Loss of fine texture discrimination	-Loss of stereognosis and thermal discrimination. -Deep pressure and pain sensation retained. -Proprioception retained.
No response at the site tested	**Deep pressure sensation loss:** (threshold > 300 gf – no response to 300 gf nylon). -Loss of graphaesthesia. -Loss of fine texture discrimination.	-Loss of stereognosis and thermal discrimination. -Loss of deep pressure sensation. -Pain sensation may persist. -Proprioception may still be present.

CLEANING THE FILAMENTS:

The aesthesiometer monofilaments can be used for testing many patients, provided that the necessary care is taken for hygienic purposes.
The object of cleaning is to reduce the risk of infection and the spread of pathogens.
Brief instructions for use and cleaning of the instrument accompany the SORRI kit.

- It is recommended to carefully wash the filaments immediately after use, avoiding stretching or crushing the filament in the process.
- A liquid soap solution in warm water can be used, optionally with 4% chlorhexidine, but avoiding other additives, especially iodine and its compounds (PVP, iodophor, etc).
- Then wipe with 70% ethyl alcohol and allow the filament to dry.
- It is not recommended to use isopropyl alcohol, as nylon is reported to have a relatively low resistance to this liquid.
- The filaments should not be left to soak because the absorption of water or alcohol may cause temporary changes in the elasticity of the nylon.
- The set is not designed to withstand the high temperature sterilization processes.
- Under ideal conditions the esthesiometer can maintain its accuracy for many years, but after a period of 18 months of use, it is recommended to replace the instrument to avoid changes in the calibration, which may occur with time as a result of the accumulation of small chemical and physical effects.
- Any filament presenting sign of damage (wrinkled, bent, cracked, etc.) must be replaced. The kit already includes reserve filaments of each size and replacement units can also be purchased at SORRI.

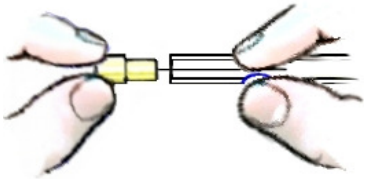
TAKING CARE OF YOUR FILAMENTS:

1. Keep the filaments out of the sun and protected from UV light sources.

2. Prevent the filaments from coming into contact with chemical reagents (acids, alkalis, oxidizing agents, among others)

3. Keep in a dark, dry and well ventilated place.

4. As you store each filament carefully after use, it is a good idea to cover the transversal mounting holes with finger and thumb to prevent the end of the filament from escaping and being damaged.



5. If a filament shows signs of damage (e.g. sharp bend, break, hardening, undulations), it should be discarded. Replacement filaments can be obtained at SORRI.

6. It is important to allow the filaments to rest for 24 hours after repeated use (BOOTH & Young, 2000). Switch to reserve filaments after every 100 "touches" or after testing with 10 patients on the same day - remember that the SORRI set provides reserve filaments.

7. Before starting the test, always bend each filament twice as a "warm-up". (Bell-Krotoski, 1989; BOOTH & YOUNG, 2000).

FAQs – Frequently Asked Questions

SETS OF SIX - OR SETS OF TWENTY MONOFILAMENTS?

The SORRI kit, composed of 6* selected diameters of Nylon 612 monofilament, was designed for convenience and efficiency in evaluating functional sensitivity thresholds of the peripheral nerves of the hands and feet.

The use of a reduced number of filaments to identify important functional thresholds was established by Werner and Omer, (1970), validated by Bell Krotoski (1990). A sixth filament was added following widespread acceptance of the proposals of Birke and Sims (1986).

In some research projects that aim to investigate subtle changes of sensitivity in other parts of the body, a denser grid may be justifiable, with smaller increments of discrimination, such as is offered by the set of 20 monofilaments.

These sets are not available from SORRI.

* (The Standard Kit contains six different filament diameters - each with a second filament in reserve, except for the most delicate, green filament which comes with three reserves - constituting a total of 14 filaments in seven protective tubes.)

SENSATION of 10 g FILAMENT DEMONSTRATES a HEALTHY FOOT?

Q. According to the instructions accompanying the Kit, if a patient cannot feel the lighter filaments at a given site, but responds affirmatively to the touch of the 10 g (Orange) filament, the interpretation suggested would be: “Definite loss of protective sensation for the foot. Pressure and pain may still be felt in hands and feet.” and the location should be mapped with a red **X**. Why then, when screening with a single 10 g filament, would the patient be classified as not at high risk?

A. The apparent conflict that arises when comparing this protocol with the use of a single filament of 10 grams for rapid screening to identify patients at high risk for foot ulcers - (especially diabetic foot), is a question of degree of risk.
The importance of being able to feel pain already appears in the teaching of Paul Brand in the 50s, but the term "Protective Sensation" only seems to date back to the work of Kilulu von Prince and Bruce Butler (1967), who demonstrated that the ability to feel the 4 grams force filament, as the lightest filament noticeable at a given site, is evidence for the absence of protective sensation in the case of the hands and sometimes of the foot. When the patient is unable to feel that filament on the foot, but only feels the 10 grams force filament, protective sensation is already also lost in the foot.
Despite the ready availability, at the time, of the 20 filament sets used by Weinstein and Semmes, the observations of Birke and Sims (1986) were based on tests using only the filaments of 1, 10 and 75 grams force. Kumar and colleagues (1991), testing close to existing ulcers, also found that no patient already with foot ulcer could feel the touch of a filament of 10 grams or less at these sites.
But the risk precedes the ulcer. Worth looking carefully at the work mentioned below.

Souza A, Nery C A S, Marciano L H S C, Garbino J A - Avaliação da neuropatia periférica: correlação entre a sensibilidade cutânea dos pés, achados clínicos e eletroneuromiográficos. ACTA FISIATR 2005; 12(3): 87-93.

In the discussion appears:

> "Several studies have been conducted to investigate the reliability of the use of monofilament in peripheral neuropathies and, at the same time, to determine the limits of perception that may cause harm to patients with sensory loss. Thus, Birke and Sims were the first to set the

level of protective sensation for assessment of leprosy and diabetic patients with plantar ulcer, using monofilaments 4.17, 5.07 and 6.10 that correspond to the force of 1g, 10g and 75g, respectively. The cited authors found that no patient with a foot ulcer could feel the 5.07 (10g) monofilament, and concluded, as other subsequent studies, that this filament is the best indicator of protective sensation and a valid tool in predicting patients at risk of plantar lesions..."

...

"In the present study, although it is considered as a loss of protective sensation **to feel** the touch of the 4g monofilament, it was observed that patients who showed a more severe clinical picture exceeded this limit, going on **to feel** only the monofilament immediately higher in the scale. No plantar ulcer was observed situated at the level of sensitivity of the 4g monofilament.

The monofilament 5.07 (10g) seems to be a warning sign for diabetes patients because complications become more frequent at this level, which shows loss of mechanism for protection and defense of the feet. That should put both patient and physician on the alert, to effectively initiate preventive measures, through a consistent program aimed at maintaining the integrity of the feet."

(Emphasis added)

Others:

Von Prince K, Butler B Jr. Measuring sensory function of the hand in peripheral nerve injuries. Am J Occup Ther. 1967;21(6):385-95.

Kamei N, Yamane K, Nakanishi S, Yamashita Y, Tamura T, Ohshita K, et al. Effectiveness of Semmes-Weinstein monofilament examination for diabetic peripheral neuropathy screening. J Diabetes Complications. 2005;19(1):47-53.

Birke JA, Sims DS. Plantar sensory threshold in the ulcerative foot. Lepr Rev. 1986;57(3):261-7.

Boyko EJ, Smith DG, Ahroni JH. A propective study of risk factors for diabetic foot ulcer. Rehabil RD Progress Reports. 1994;32:318-9.

Rith-Najarian SJ, Stolusky T, Gohdes DM. Identifying diabetic patients at high risk for lower-extremity amputation in a primary health care setting. A prospective evaluation of simple screening criteria. Diabetes Care. 1992;15(10):1386-9.

TERMINOLOGICAL CONFUSION: FORCE / PRESSURE / "M"?

Semmes-Weinstein monofilaments were originally chosen from the commercially available nylon fibre sizes, which were by diameter, in thousandths of an inch, whole numbers only. A selection was made of twenty suitable diameters from the range between 2 and 45. Once cut to length, these could be identified by diameter, or, more usefully, by the critical axial force necessary to initiate buckling. This value was obtained directly by measurement, in the laboratory.

Despite the use of the word “pressure” in the literature, the actual pressure transmitted may only be obtained by calculation, because it depends on this force and also on the contact area, which may vary during the application of the filament.

Further, the same pressure value might be applied by a heavy force distributed over a large area as by a light force over a relatively small area, and this would have very different effects on the nerves.
Thus, in general, manufacturers tend to use the established units of force instead of some estimate of "pressure" or "stress" to identify each monofilament.

In the past, to facilitate graphic demonstrations - (since a logarithmic scale of applied forces approximates a linear scale of the perceived strength), this was done by using the variable "M," which is calculated as the logarithm of ten times the force in milligrams required to bow the filament:

$$M = \log (10.Fmg)$$

Thus the filaments were marked with a number such as "**2.83**" or "**3.61**", etc.

Some manufacturers still use this system, despite the problems of interpretation that it generates. In fact this practice was already identified as a source of potential confusion in the article by Scott Levin, back in 1978.

The problem is further complicated in some studies where the logarithmic value is associated with the acronym MN ("Marking Number"), easily confused with mN or milinewtons - unit of force accepted in the International System of Units (SI).

At the suggestion of specialists from the Research Department of the Leprosy Center in Carville, Louisiana, when developing the Sensitivity Testing Kit, SORRI eliminated this complication in the identification of their filaments, by using the simple force value. The value is marked in grams force (or simply “g”) and represents the rounded value of the force necessary to initiate a bend in the filament during correct application of the test.

Today many other models of monofilament aesthesiometer also adopt this more rational system.

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ABOUT "SORRI"

SORRI, which means "SMILE" in Portuguese, is a Brazilian non-governmental organisation (NGO), founded in 1976 in the town of Bauru. Its purpose was to remedy the local lack of services for disabled people and, at the same time, to help break down the stigma associated with the disease of Leprosy (Hansen's disease). It is a non-profit rehabilitation centre, and has gradually opened the scope of its mission, which, through a wide range of services and activities, now aims toward the long-term empowerment of disabled people and their families, and the construction of an inclusive society.
The manufacture and distribution of the monofilament skin sensitivity testing kit is one of the ways that SORRI participates in the prevention of disabilities, while revenue from the sales helps to maintain the quality of services provided without cost to disabled members of the community.

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